NOV 1 6 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K013095 **"**

Introduction

According to the requirements of 21 CFR 862.1580, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Tel: 54 341 4329191
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Contact person: Viviana Cétola
Date Prepared: July 25, 2001

6-2 Device Name

Proprietary name: Wiener lab. FOSFATEMIA UV AA

Common name: Phosphorus (inorganic) test system

Classification name: Phosphomolybdate (Colorimetric), Inorganic Phosphorus, CEO, as per 21 CFR section 862.1580.

Device Class I

6-3 Predicate Device

We claim substantial equivalence to the currently marketed ROCHE DIAGNOSTICS / BOEHRINGER MANNHEIM CORP. INORGANIC PHOSPHORUS test system (Cat. Nº 836281)

6-4 Device Description

End point method.

Inorganic phosphate reacts with molybdate in the presence of acid to form a phosphomolybdate complex that is measured photometrically at 340 nm.

6-5 Intended Use

The FOSFATEMIA UV AA test system is a device intended to measure inorganic phosphorus in serum, plasma and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

6-6 Equivalencies and Differences

The Wiener lab. Inorganic Phosphorus test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ROCHE DIAGNOSTICS / BOEHRINGER MANNHEIM CORP. INORGANIC PHOSPHORUS test system.

The following table illustrates the similarities and differences between the Wiener lab. Inorganic Phosphorus test system and the currently marketed ROCHE DIAGNOSTICS / BOEHRINGER MANNHEIM CORP. INORGANIC PHOSPHORUS test system.

	ROCHE/BOEHRINGER Test System	**WIENER LAB. Test System**
Intended Use	Method for measurement of inorganic phosphorus.	
		Continued on next page

	ROCHE/BOEHRINGER Test System	WIENER LAB. Test System
Test Principle	End point method. Inorganic phosphate reacts with molybdate in the presence of sulfuric acid to form a phosphomolybdate complex that is measured photometrically at 340 nm.	
Essential Components	Ammonium molybdate – Sulfuric acid	
Reagents	R1: Sulfuric acid and detergent. R2: Sulfuric acid, Amonium molybdate and Sodium chloride.	R: Sulfuric acid and Amonium molybdate.
Instability or Deterioration of Reagents	Not specified	Absorbance of Reagent > 0.500.
Working Temperature Range	25 – 37ºC	
Stability of Final Color	Not specified	20 minutes
Wavelength of Reading.	340 nm	
Calibration	Single point	
Linearity	20 mg/dl	16 mg/dl
Minimum Detection Limit	Not specified	0.11 mg/dl

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 6 2001

Dr. Viviana Cétola
QC/QA Manager
Wiener Laboratorios S.A.I.C.
2944 Riobamba
Rosario, Santa Fe
Argentina

Re: K013095
Trade/Device Name: Wiener Lab. Fosfatemia UV AA Test System
Regulation Number: 21 CFR 862.1580
Regulation Name: Phosphorus (inorganic) Test System
Regulatory Class: I
Product Code: CEO
Dated: August 13, 2001
Received: September 17, 2001

Dear Dr. Cétola:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013095

NOV 1 6 2001

510(k) Number (if known): K013095

Device Name: Wiener lab.
Fosfatemia UV AA

Indications For Use:

The "Wiener lab. Fosfatemia UV AA" test system is a quantitative in vitro diagnostic device intended to measure inorganic phosphorus in serum, plasma and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

(Division Sign-Off)
Division of Clinical Labo[illegible]ices
510(k) Number K013095

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

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